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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TIMOTHY JAMES JEGLA

Appeal 2008-3593
Application 10/815,297
Technology Center 1600

Decided: November 5, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 12-14 and 16-18. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The claims are directed to an isolated polypeptide comprising an alpha subunit of a Kv potassium channel. "Potassium channels are involved in a number of physiological processes, including regulation of heartbeat, dilation of arteries, release of insulin, excitability of nerve cells, and regulation of renal electrolyte transport" (Spec. 1: 13-15). "Potassium channels are made by alpha subunits that fall into 8 families, based on predicted structural and functional similarities" (*id*. at 1: 23-25). The Kv superfamily represents voltage-gated potassium channels which are "found in a wide variety of tissues and cell types and are involved in processes such as neuronal integration, cardiac pacemaking, muscle contraction, hormone section, cell volume regulation, lymphocyte differentiation, and cell proliferation (*id*. at 2: 19-22).

Claims 12-14 and 16-18 are pending. Appellant appeals the final rejection of the pending claims for failing to comply with the utility and enablement requirements under 35 U.S.C. §§ 101 and 112, first paragraph, respectively (Ans. 2). Claim 12, which is representative of the claimed subject matter, reads as follows:

> 12. An isolated polypeptide comprising an alpha subunit of a Kv potassium channel, the polypeptide:
> (i) forming, with at least one additional Kv alpha subunit, a Kv potassium channel having the characteristic of voltage-gating; and
> (ii) comprising an amino acid sequence having at least 90% sequence identity to SEQ ID NO:3.

ISSUE

The Examiner contends that there is no evidence that the claimed polypeptides have "an established biological role in a particular disease, disorder or physiological process which one would wish to manipulate for a desired clinical effect" and therefore concludes that it does not have a specific, substantial, and credible utility (Ans. 3-4). Appellants contend that adequate evidence has been provided of utility which conforms to the statutory requirement under 35 U.S.C. § 101.

The issue in this appeal is whether the claimed isolated nucleic acid polypeptide comprising an alpha subunit of a Kv10 potassium channel meets the utility requirement of 35 U.S.C. § 101.

PRINCIPLES OF LAW

The "utility requirement" originates with the provision of 35 U.S.C. § 101 that a patent may be obtained on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." An inquiry by the Patent Office into whether a claimed invention satisfies the utility requirement typically has two distinct prongs. First, the Patent Office must determine whether the patent applicant has asserted a specific and substantial utility for the claimed invention. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). Second, the Patent Office must ascertain whether there is any evidence that one of ordinary skill in the art would reasonably doubt the invention's asserted utility. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

FINDINGS OF FACT (FF)

1. An isolated polypeptide comprising an alpha subunit of a Kv potassium channel is claimed.

2. According to the Specification, the claimed polypeptides (exemplified by Kv10.1) are members of the Kv family of voltage-gated potassium channels and are involved in neuronal excitability (Spec. 8: 14-29).

3. Kv10.1 has sequence identity to other potassium channel family members (Spec. 6: 31 to 7: 7; *see* Figs. 1 and 2).

4. The Specification shows that, when Kv10.1 is expressed by itself in oocytes, it is electrically silent (Spec. 63: 2-5).

5. However, when Kv10.1 is co-expressed with other potassium channel subunits, it modifies their conductance (Spec. 63: 6-8).

6. Co-expressed with the Kv2.1 channel protein, Kv10.1 reduces potassium current; with Kv2.2, it forms functional heteromers which are voltage-gated, "but activate and deactivate more rapidly than Kv2.2 homomultimers" (Spec. 63: 2-15).

7. Kv10.1 is expressed in the central nervous system and retina (Spec. 64: 13-20).

8. Kv2.1 and Kv2.2 are also expressed in the retina (Spec. 64: 15-16).

9. Because of its pattern of tissue expression, the Specification states that "modulators of potassium channels containing Kv10.1 subunits are useful in treating a variety of CNS disorders that involve abnormalities in excitability" (Spec. 64: 18-20).

10. Visual disorders are among a list of CNS disorders that can be treated with Kv10.1 modulators (Spec. 3: 8-9; 64: 27-29).

11. Appellant provides a Declaration under 37 C.F.R. § 1.132 by Dr. Douglas S. Krafte, an employee of the assignee of the pending application (Krafte Dec. ¶ 2).

12. Dr. Krafte cites a post-filing publication (Wu et al., *Am. J. Hum. Genet.* 79: 574-79, 2006) describing mutations in the Kv10.1 gene ("KCNV2") "that are responsible for a specific vision disorder, which is characterized by reduced visual acuity, photoaversion, night blindness, and abnormal color vision" (Kraft Dec. ¶ 6).

13. A divisional application of the pending application has already issued as U.S. Patent No. 6,727,353. Claim 1 of the issued patent recites:

> An isolated nucleic acid encoding a polypeptide comprising an alpha subunit of a Kv potassium channel, the polypeptide: (i) forming, with at least one additional Kv alpha subunit, a Kv potassium channel having the characteristic of voltage-gating; and (ii) comprising an amino acid sequence having at least 90% amino acid sequence identity to SEQ ID NO:3.

ANALYSIS

Utility rejection

The issue in this appeal is whether the claimed isolated nucleic acid polypeptide comprising an alpha subunit of a Kv10 potassium channel meets the utility requirement of 35 U.S.C. § 101. The Examiner contends that there is no evidence that the claimed polypeptide has "an established biological role in a particular disease, disorder or physiological process which one would wish to manipulate for a desired clinical effect" and therefore concludes that it does not have a specific, substantial, and credible utility (Ans. 3-4).

The "utility requirement" originates with the provision of 35 U.S.C.

§ 101 that a patent may be obtained on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." An inquiry by the Patent Office into whether a claimed invention satisfies the utility requirement typically has two distinct prongs. First, the Patent Office must determine whether the patent applicant has asserted a specific and substantial utility for the claimed invention. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). Second, the Patent Office must ascertain whether there is any evidence that one of ordinary skill in the art would reasonably doubt the invention's asserted utility. *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

In this case, the claimed polypeptide is asserted to be useful because it is a potassium channel subunit involved in neuronal excitability (FF2) and therefore modulators of it can be used to treat CNS disorders "that involve abnormalities in excitability," particularly in the visual system (FF2, 9, 10). In support of this utility, the Specification shows that the Kv10.1 is structurally related to other potassium channel polypeptides (FF3). The Specification also provides experimental evidence that Kv10.1 associates with other potassium channel subunits, forms voltage-gated channel heteromers with the Kv2.2 channel protein, and is expressed in the CNS and retina (FF5-7).

Post-filing evidence substantiates the assertion in the Specification that Kv10.1 is involved in visual disorders. In a Declaration by Dr. Douglas S. Krafte (FF11), a post-filing 2006 publication is cited that shows mutations in the Kv10.1 gene "are responsible for a specific vision disorder, which is characterized by reduced visual acuity, photoaversion, night blindness, and abnormal color vision" (FF12; Kraft Dec. ¶ 6).

The Examiner asserts that there is no evidence that "a protein of the instant invention naturally forms a heteromultimeric voltage gated potassium channel in combination with Kv 2.2" (Ans. 3). This argument is not convincing. Appellant has provided evidence that Kv10.1 affects the voltage-gating properties of Kv2.2 (FF6) and thus it would be reasonably concluded by persons of ordinary skill in the art that the two proteins associate and form multimers with each other. Furthermore, the Specification shows that Kv10.1 and Kv2.2 are both expressed in the retina (FF7, 8). Based on this evidence, we find that it is reasonable to conclude that Kv10.1 and Kv2.2 heteromers are present in the visual system as asserted (Spec. 64: 13-20). The Examiner has not provided any evidence to doubt this.

The Examiner acknowledges structural similarity to other potassium channel family members and experimental evidence of channel function (*see* FF3-6), but asserts that this information is insufficient "to establish a nexus between the structure and/or function of a Kv10 protein of the instant invention and the etiology of a particular disease or disorder" (Ans. 5-7).

This argument is not persuasive. Appellant has provided sound scientific reasoning for their conclusion that Kv10.1 is a channel involved in neuronal excitability. This reasoning is based on structural (FF3), functional (FF4-6), and expression data (FF7-8) – the types of information ordinarily relied upon in the art to determine a polypeptide's physiological role.

> [T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. . . . Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to

> convince such a person of the invention's asserted utility. *See In re Bundy*, 642 F.2d 430, 433 (CCPA 1981).

Brana, 51 F.3d at 1566. In this case, the Examiner has not provided any scientific reason to doubt Appellant's credible and scientifically based assertion about the claimed polypeptide's function.

As far as establishing a "nexus" between Kv10 and a disease or disorder (Ans. 6-7), we do not agree that a disease association is necessary to meet the utility requirement. As argued by Appellant, the claims are not directed to a therapeutic use and therefore identification of a specific disease or disorder is not necessarily needed (Reply Br. 6). To comply with Section 101, an asserted utility must be both specific and substantial. *In re Fisher*, 421 F.3d at 1371. Appellant has provided adequate evidence that the claimed polypeptide is a potassium channel protein which has a well established physiological role in neuronal excitability (Reply Br. 7; Spec. 1-2). We conclude that such an *in vivo* role is specific as it represents a specific biological property (*see Cross v. Iizuka*, 753 F.2d 1040, 1048 (Fed. Cir. 1985); it is also substantial in that Kv10.1 can be used to identify channel modulators and study diseases associated with it (App. Br. 7; Krafte Dec. ¶ ¶ 7-8). Indeed, as asserted in the Specification, Kv10.1 was subsequently found to be involved in a visual system disorder (FF12). Kv101.1 is not an orphan protein as asserted by the Examiner (Ans. 4), but a polypeptide which the preponderance of the evidence establishes has potassium channel activity and a role in visual system activity. Thus, we reverse this rejection.

§ 112, first paragraph rejection

Claims 12-14 and 16-18 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that "since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention" (Ans. 8). As we do not agree with the Examiner's determination that the claimed invention lacks utility under § 101, we also reverse the rejection under § 112, first paragraph.

CONCLUSION OF LAW

As the Examiner erred in concluding that the claimed isolated nucleic acid polypeptide comprising an alpha subunit of a Kv10 potassium channel fails to meet the utility requirement, we reverse the rejection of claims 12-14 and 16-18 under 35 U.S.C. §§ 101 and 112, first paragraph.

REVERSED

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